VICH GLs: data to be provided to apply for waiving of TABST (and LABST in future)

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Background to VICH

- VICH = The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

- 1996: animal health industry and regulators from the European Union, Japan and the United States with Australia/New Zealand and Canada joining as observers.
  - Harmonise regulatory requirements in the VICH regions to ensure high quality, safety and efficacy standards, even as it reduces the number of animals needed for testing and the associated costs;
  - Provide a basis for wider international harmonisation of registration requirements;
  - For more information: http://www.vichsec.org/

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Status of VICH GL development

• EU launched discussion in 2008
• VICH decision to focus on TABST
  • GL50 (live vaccines) published in 2013 to be implemented by 2014
  • Revised GL50 and GL55 (inactivated vaccines) published in 2018 to be implemented by 2019
  • GL50 & 55 included in OIE manual 2018
• Work on LABST GL started in 2016
  • Data collection served as basis
Criteria for waivers

Manufacturers:

- demonstrate that the product is produced following VICH principles (e.g. seed lot system, quality control & assurance, pharmacovigilance);
- present data of a suitable number of batches (e.g. 10 or less, e.g. 5, if 10 batches are not produced within 3 years);
- can use data from combined vaccines
- provide a dossier for each vaccine; and
- apply for waivers with regulatory authority.

- Regulatory authorities decide on waivers.
Thank you!

Questions?

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